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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

APPEAL BRIEF TRANSMITTAL and PETITION FOR EXTENSION OF TIME		Docket Number: **2565/93**	
Application Number: **09/973,968**	Filing Date: **October 9, 2001**	Examiner: **Aamer S. Ahmed**	Art Unit: **3763**
Title: **Method for Determining the Intraperitoneal Volume and Device For Peritoneal Dialysis**		Inventors: **Joachim NOACK**	

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Date: January 30, 2006

Signature: _____
Kevin T. Godlewski (Reg. No. 47,598)

Sir:

Transmitted herewith for filing is an Appeal Brief in support of the Notice of Appeal filed October 31, 2005.

The Commissioner is hereby authorized to charge payment of the Appeal Brief fee of **$500.00** to the deposit account of Kenyon & Kenyon LLP, deposit account number 11-0600.

In addition, Applicant respectfully requests a **one-month extension of time** for filing the enclosed Appeal Brief. The one-month extended period for response expires on January 31, 2006. The fee for a one month extension of time is **$120.00**, and Applicant hereby authorizes the Commissioner to charge this fee to the deposit account of Kenyon & Kenyon LLP, deposit account number 11-0600.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account 11-0600. A duplicate of this paper is attached for that purpose.

Respectfully submitted,

Date: January 30, 2006 By: _____
Kevin T. Godlewski (Reg. No. 47,598)

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PATENT

Docket No. 2565/93

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Inventor	:	Joachim **NOACK**
Serial No.	:	09/973,968
Filed	:	October 9, 2001
For	:	**METHOD FOR DETERMINING THE INTRAPERITONEAL VOLUME AND DEVICE FOR PERITONEAL DIALYSIS**
Examiner	:	Aamer S. Ahmed
Art Unit	:	3763

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Kevin T. Godlewski (Reg. No. 47,598)

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

S I R :

On October 28, 2005, Appellant mailed a Notice of Appeal (which was filed by the U.S. Patent and Trademark Office ("the Patent Office") on October 31, 2005) from the final rejection of claims 1-5 contained in the Final Office Action mailed by the Patent Office on May 18, 2005 in the above-identified patent application.

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In accordance with 37 C.F.R. § 41.37, this Brief is submitted in support of the appeal of the final rejection of claims 1-5. For at least the reasons set forth below, the final rejection of claims 1-5 should be reversed.

I. REAL PARTY IN INTEREST

The real party in interest is FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH, having a principal place of business at Else-Kröner-Strasse 1, D-61352 Bad Homburg, Federal Republic of Germany. FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH is the assignee of the entire right, title and interest in and to this application.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH, "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

III. STATUS OF CLAIMS

Claims 1-5 are pending in the above-identified patent application, as claims 6-10 have been cancelled.

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over: (1) U.S. Patent No. 5,643,201 to Peabody *et al.* ("Peabody *et al.*") in view of U.S. Patent No. 4,668,400 to Veech ("Veech"); (2) U.S. Patent No. 5,542,919 to Simon *et al.*

("Simon *et al.*") in view of Veech; (3) U.S. Patent No. 3,620,215 to Tysk *et al.* ("Tysk *et al.*") in view of Veech; (4) European Patent Application No. 0 149 001 ("EPA 0 149 001") in view of Veech; and (5) U.S. Patent No. 6,409,699 to Ash ("Ash") in view of Veech.

Appellant appeals from the final rejection of claims 1-5 made in the Final Office Action mailed by the Patent Office on May 18, 2005. The claims on appeal (*i.e.*, claims 1-5), in their present form and after entry of all amendments entered during the course of prosecution, are set forth in the Claims Appendix attached hereto.

IV. STATUS OF AMENDMENTS

A "Response to Office Action Under 37 C.F.R. § 1.116" was mailed to the Patent Office on July 18, 2005. In the "Response to Office Action Under 37 C.F.R. § 1.116," amendments were made to claims 1 and 2. An Advisory Action was mailed by the Patent Office on September 28, 2005, indicating that these claim amendments would be entered for purposes of appeal. As such, it is believed that the claim amendments included in the "Response to Office Action Under 37 C.F.R. § 1.116" have been entered, and the appealed claims that appear in the Claims Appendix reflect entry of these claim amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to a method for determining an intraperitoneal volume during peritoneal dialysis. The method includes passing a peritoneal solution from a peritoneal cavity in a first circuit adjacent a first side of a semipermeable membrane, and passing a dialyzing fluid in a second circuit adjacent a second side of the semipermeable membrane. Specification, page 3, lines 13-14; page 6, lines 1-2; and figure 1. The method also includes measuring the concentration of an endogenous substance in the

peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity. *Id.*, page 3, lines 7-9; page 4, lines 1-2; and page 7, lines 21-22. Furthermore, the method includes determining the intraperitoneal volume from the variation in the concentration of the endogenous substance over time. *Id.*, page 3, lines 7-9; page 4, lines 21-24; page 7, line 28 to page 8, line 1; and figures 2a, 2b, 2c.

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

A. Whether claims 1-5, which stand rejected under 35 U.S.C. § 103(a), are patentable over Peabody *et al.* in view of Veech.

B. Whether claims 1-5, which stand rejected under 35 U.S.C. § 103(a), are patentable over Simon *et al.* in view of Veech.

C. Whether claims 1-5, which stand rejected under 35 U.S.C. § 103(a), are patentable over Tysk *et al.* in view of Veech.

D. Whether claims 1-5, which stand rejected under 35 U.S.C. § 103(a), are patentable over EPA 0 149 001 in view of Veech.

E. Whether claims 1-5, which stand rejected under 35 U.S.C. § 103(a), are patentable over Ash in view of Veech.

VII. ARGUMENTS

A. Rejection of Claims 1-5 Under 35 U.S.C. § 103(a) as Being Unpatentable over Peabody *et al.* in view of Veech

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Peabody *et al.* in view of Veech. Specifically, the Patent Office has stated that "it would have been obvious to modify the invtion [sic] disclosed by Peabody et al. ... by measuring

the concentration of an endogenous solution as taught by Veech." Advisory Action mailed September 28, 2005, page 2. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

To establish a *prima facie* case of obviousness, the Patent Office must demonstrate three criteria: (1) there must be some suggestion or motivation to one of ordinary skill in the art to modify a reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest each and every limitation in the claim under examination. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The presently claimed invention is directed to a method for determining an intraperitoneal volume during peritoneal dialysis. Specifically, independent claim 1, and dependent claims 2-5 therefrom, include the claim limitation of "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity." As described in the present specification, this method of the present invention is advantageous "in that exogenous substances need not be added. Therefore, determination of the intraperitoneal volume is less cumbersome and less costly. In addition, incompatibilities can be ruled out." Specification, page 3, lines 9-11.

Peabody *et al.* is directed to a continuous peritoneal dialysis apparatus. The method described in Peabody *et al.* "includes accumulating a sterilized dialysis fluid in a first reservoir, weighing the dialysis fluid in the first reservoir to determine a first prescribed volume of dialysis fluid, and filling a peritoneal cavity of a patient with the first prescribed volume of dialysis fluid from the first reservoir. Next, the method includes draining the

dialysis fluid from the peritoneal cavity of the patient into a second reservoir, weighing the dialysis fluid in the second reservoir to determine a second prescribed volume of dialysis fluid, and terminating the draining of the dialysis fluid from the peritoneal cavity in response to weighing of the second prescribed volume of dialysis fluid in the second reservoir. The volume of fluid in the peritoneal cavity of the patient is monitored and the amount of dialysis fluid in the peritoneal cavity is adjusted to provide a desired volume in the peritoneal cavity." Peabody *et al.*, col. 5, lines 21-36. However, Peabody *et al.* do not disclose "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Veech does not cure the shortcomings of Peabody *et al.* Veech is generally directed to hemodialysis processes and hemodialysis solutions. Veech allegedly discloses "[t]echniques for predicting the respective concentrations and distributions of diffusible materials in solutions on opposing sides of a semi permeable membrane." Veech, abstract. According to the disclosure of Veech, "the concentrations and distributions of electrolytes in, respectively: (a) the freshly hemodialyzed blood of a patient, and (b) the hemodialysis solution used for the hemodialysis of that patient's blood, are defined by certain mathematical relationships which closely approximate such concentrations and distributions in each of the hemodialyzed blood and the hemodialysis solution[, which] ... permits one to practice various new and very useful processes in the field of hemodialysis[, such as] ... preparing an aqueous hemodialysis solution which when used for hemodialysis of a given patient will produce in the blood (plasma) being returned to such patient after hemodialysis thereof a desired or predicted composition of electrolytes." Veech, col. 8, lines 33-49. Veech further discloses that "[i]n such a process, one measures the approximate molar concentration of the albumin

initially present *in the blood of the patient* to be hemodialyzed with such desired solution." Veech, col. 23, lines 55-58 (emphasis added). As stated in Veech, "[v]arious teohniques [sic] are available for measuring albumin content in mammalian blood and any convenient such technique can be employed in the practice of this invention." Veech, col. 23, lines 58-61. That is, Veech discloses the measuring of albumin content in mammalian blood, rather than the measuring of the concentration of albumin in "the peritoneal solution." Thus, Veech does not teach nor suggest "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Since neither Peabody *et al.* nor Veech, alone or in combination, teaches or suggests "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity" as recited in independent claim 1, there would be no motivation to combine these two patents in an attempt to arrive at the claimed invention of Appellant's independent claim 1. Furthermore, even if one skilled in the art were to combine Peabody *et al.* and Veech, one would not achieve the subject matter of independent claim 1 as each and every element of this claim is not taught nor suggested. Accordingly, independent claim 1 is not rendered obvious by the combination of Peabody *et al.* and Veech. As claims 2-5 ultimately depend from claim 1, the above arguments regarding independent claim 1 apply equally to dependent claims 2-5. Reversal of these rejections is respectfully requested.

B. Rejection of Claims 1-5 Under 35 U.S.C. § 103(a) as Being Unpatentable over Simon *et al.* in view of Veech

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simon *et al.* in view of Veech. Specifically, the Patent Office has stated that "it would have

been obvious to modify the invtion [sic] disclosed by ... Simon et al. ... by measuring the concentration of an endogenous solution as taught by Veech." Advisory Action mailed September 28, 2005, page 2. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

As more fully described above, independent claim 1, and dependent claims 2-5 therefrom, include the claim limitation of "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Simon *et al.* is directed to a peritoneal dialysis device. The device disclosed in Simon *et al.* "has a balancing chamber that is divided into two halves by a movable, liquid-impermeable wall. The amount of liquid introduced into one half displaces the amount of fluid present in the other half in exact volumetric correspondence by displacement of the wall. As a result of this, the inlet and outlet volume can be determined with high accuracy, with an accuracy of one chamber volume (approx. 1% error), so that the ultrafiltered amount can also be determined accurately too." Simon *et al.*, col. 2, lines 47-55. However, Simon *et al.* do not disclose "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

As more fully described above, Veech is generally directed to hemodialysis processes and hemodialysis solutions. However, Veech also does not teach nor suggest "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Since neither Simon *et al.* nor Veech, alone or in combination, teaches or suggests "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity" as recited in independent claim 1, there would be no motivation to combine these two patents in an attempt to arrive at the claimed invention of Appellant's independent claim 1. Furthermore, even if one skilled in the art were to combine Simon *et al.* and Veech, one would not achieve the subject matter of independent claim 1 as each and every element of this claim is not taught nor suggested. Accordingly, independent claim 1 is not rendered obvious by the combination of Simon *et al.* and Veech. As claims 2-5 ultimately depend from claim 1, the above arguments regarding independent claim 1 apply equally to dependent claims 2-5. Reversal of these rejections is respectfully requested.

C. Rejection of Claims 1-5 Under 35 U.S.C. § 103(a) as Being Unpatentable over Tysk *et al.* in view of Veech

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tysk *et al.* in view of Veech. Specifically, the Patent Office has stated that "it would have been obvious to modify the invtion [sic] disclosed by ... Tysk et al. ... by measuring the concentration of an endogenous solution as taught by Veech." Advisory Action mailed September 28, 2005, page 2. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

As more fully described above, independent claim 1, and dependent claims 2-5 therefrom, include the claim limitation of "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Tysk *et al.* is directed to an apparatus for peritoneal dialysis. Tysk *et al.* discloses "[a]n apparatus for peritoneal dialysis treatment of a patient operating automatically in accordance with a predetermined program comprising a plurality of successive dialysis cycles each consisting of a fill-phase during which fresh dialysis fluid is introduced into the peritoneal cavity of the patient, a dialysis-phase during which the dialysis fluid remains in the peritoneal cavity, and a drain-phase during which the used dialysis fluid is withdrawn from the peritoneal cavity of the patient." Tysk *et al.*, abstract. However, Tysk *et al.* do not disclose "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

As more fully described above, Veech is generally directed to hemodialysis processes and hemodialysis solutions. However, Veech also does not teach nor suggest "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Since neither Tysk *et al.* nor Veech, alone or in combination, teaches or suggests "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity" as recited in independent claim 1, there would be no motivation to combine these two patents in an attempt to arrive at the claimed invention of Appellant's independent claim 1. Furthermore, even if one skilled in the art were to combine Tysk *et al.* and Veech, one would not achieve the subject matter of independent claim 1 as each and every element of this claim is not taught nor suggested. Accordingly, independent claim 1 is

not rendered obvious by the combination of Tysk *et al.* and Veech. As claims 2-5 ultimately depend from claim 1, the above arguments regarding independent claim 1 apply equally to dependent claims 2-5. Reversal of these rejections is respectfully requested.

D. Rejection of Claims 1-5 Under 35 U.S.C. § 103(a) as Being Unpatentable over Tysk *et al.* in view of Veech

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EPA 0 149 001 in view of Veech. Specifically, the Patent Office has stated that "it would have been obvious to modify the invtion [sic] disclosed by ... EPA 0,149,001 ... by measuring the concentration of an endogenous solution as taught by Veech." Advisory Action mailed September 28, 2005, page 2. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

As more fully described above, independent claim 1, and dependent claims 2-5 therefrom, include the claim limitation of "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

EPA 0 149 001 has been described in the background section of the present specification, as EPA 0 149 001 is directed to a peritoneal dialysis device. As described in the present specification, EPA 0 149 001 discloses a peritoneal dialysis device in which the ultrafiltration rate is controlled as a function of the intraperitoneal volume, so that "overfilling" of the patient is precluded, and wherein ultrafiltration control is based on measurement of dilution. The peritoneal dialysis device of EPA 0 149 001 comprises a closed circuit, in which dialyzing fluid circulates and to which a substance is added from outside whose secretion and resorption rate is negligible during the entire duration of treatment. The concentration of this exogenous substance in the peritoneal solution

continuously decreases with increasing volume. During treatment, the concentration of this exogenous substance is measured and compared with the initial concentration at the start of treatment. When a difference between the measured concentration and the initial concentration is detected, the ultrafiltration means withdraws fluid from the peritoneal cavity until the initial concentration in the dialyzing fluid has been reestablished. However, EPA 0 149 001 does not disclose "measuring the concentration of an endogenous substance that passes through a peritoneum into the peritoneal solution in the peritoneal cavity." In fact, as was described in the present specification, a drawback with the device disclosed in EPA 0 149 001 is that an exogenous substance must be added to the dialyzing fluid, and thus, incompatibilities cannot be ruled out. In addition, further secretion or resorption of the exogenous substance in EPA 0 149 001 may also result in defective control of the ultrafiltration rate.

As more fully described above, Veech is generally directed to hemodialysis processes and hemodialysis solutions. However, Veech also does not teach nor suggest "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Since neither EPA 0 149 001 nor Veech, alone or in combination, teaches or suggests "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity" as recited in independent claim 1, there would be no motivation to combine these two patents in an attempt to arrive at the claimed invention of Appellant's independent claim 1. Furthermore, even if one skilled in the art were to combine EPA 0 149

001 and Veech, one would not achieve the subject matter of independent claim 1 as each and every element of this claim is not taught nor suggested. Accordingly, independent claim 1 is not rendered obvious by the combination of EPA 0 149 001 and Veech. As claims 2-5 ultimately depend from claim 1, the above arguments regarding independent claim 1 apply equally to dependent claims 2-5. Reversal of these rejections is respectfully requested.

E. Rejection of Claims 1-5 Under 35 U.S.C. § 103(a) as Being Unpatentable over Ash in view of Veech

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ash in view of Veech. Specifically, the Patent Office has stated that "it would have been obvious to modify the invtion [sic] disclosed by ... Ash by measuring the concentration of an endogenous solution as taught by Veech." Advisory Action mailed September 28, 2005, page 2. It is respectfully submitted that these rejections should be withdrawn for at least the following reasons.

As more fully described above, independent claim 1, and dependent claims 2-5 therefrom, include the claim limitation of "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

Ash is directed to a continuous flow-through peritoneal dialysis (CFPD) method with control of intraperitoneal pressure. Ash discloses "devices and methods for treating patients suffering from renal insufficiency and/or hepatic insufficiency." Ash, col. 5, line 66 to col. 6, line1. The devices and methods disclosed in Ash "utilize in preferred embodiments the advantageous features of a dual lumen catheter, preferably a T-fluted dual lumen catheter, combined with a substantially constant rate of dialysate inflow and a pressure-dependent outflow controller ...." Ash, col. 6, lines 8-12. According to Ash, the

devices and methods disclosed therein "provide[] in certain aspects advantageous systems for passing fluid through a patient's peritoneal cavity at a relatively high flow rate, while maintaining in the peritoneal cavity an optimal dialysate pressure, to thereby alter the contents of the patient's blood by diffusion of molecules through the peritoneal membrane." Ash, col. 6, lines 14-19. However, Ash does not disclose "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity."

As more fully described above, Veech is generally directed to hemodialysis processes and hemodialysis solutions. However, Veech also does not teach nor suggest "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity," as is currently recited in the pending claims.

Since neither Ash nor Veech, alone or in combination, teaches or suggests "measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity" as recited in independent claim 1, there would be no motivation to combine these two patents in an attempt to arrive at the claimed invention of Appellant's independent claim 1. Furthermore, even if one skilled in the art were to combine Ash and Veech, one would not achieve the subject matter of independent claim 1 as each and every element of this claim is not taught nor suggested. Accordingly, independent claim 1 is not rendered obvious by the combination of Ash and Veech. As claims 2-5 ultimately depend from claim 1, the above arguments regarding independent claim 1 apply equally to dependent claims 2-5. Reversal of these rejections is respectfully requested.

VIII. CONCLUSION

For at least the reasons indicated above, Appellant respectfully submits that the art of record does not disclose or suggest the subject matter as recited in the claims of the above-identified application. Accordingly, it is respectfully submitted that the subject matter recited in the claims of the present application is new, non-obvious and useful.

In view of all of the foregoing, reversal of all of the rejections set forth in the Final Office Action is therefore respectfully requested.

Respectfully submitted,
KENYON & KENYON LLP

Dated: January 30, 2006 By: _____

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Appendices

CLAIMS APPENDIX

1. A method for determining an intraperitoneal volume during peritoneal dialysis, comprising the steps of:

passing a peritoneal solution from a peritoneal cavity in a first circuit adjacent a first side of a semipermeable membrane;

passing a dialyzing fluid in a second circuit adjacent a second side of the semipermeable membrane;

measuring the concentration of an endogenous substance in the peritoneal solution, wherein the endogenous substance passes through a peritoneum into the peritoneal solution in the peritoneal cavity; and

determining the intraperitoneal volume from the variation in the concentration over time.

2. The method according to claim 1, wherein the measuring step further comprises:

measuring the concentration c_0 of the endogenous substance in the peritoneal solution at a time t_1;

withdrawing or delivering a predetermined volume ΔV of fluid in the first circuit;

measuring the concentration c_1 of the endogenous substance in the peritoneal solution at a time t_2; and

wherein the determining step further comprises:

determining the intraperitoneal volume from the equation:

$$V = \frac{\Delta V}{1 - c_0 / c_1}$$

3. The method according to claim 2, which further comprises the step of:

determining an ultrafiltration rate V $(t_1)/t_1$ from the variation in intraperitoneal volume in the time $t_1 - t_2$;

withdrawing fluid from the first circuit at the ultrafiltration rate.

4. The method according to claim 3, which further comprises the step of:

determining continuously the variation in intraperitoneal volume during peritoneal dialysis for determination of the ultrafiltration rate.

5. The method according to claim 1, wherein the endogenous substance is albumin.

EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellants in the appeal.

RELATED PROCEEDINGS APPENDIX

As indicated above in Section II of this Appeal Brief, "[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH, 'which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.'" As such, there are no "decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]" to be submitted.